

Additional Business Proposal Instructions

In addition to instructions and format requirements for the Business Proposal that are contained in the solicitation, the information presented in this attachment is intended to provide uniform cost assumptions that apply to the solicitation.

Offerors are advised to give careful consideration to the Statement of Work, all reference material provided as attachments, the technical evaluation criteria, and the RFP as a whole, in the development of their proposal. The information requested here shall be used as further guidance for the development of the Business Proposal.

BUSINESS PROPOSAL

SECTION 1 – PROPOSAL COVERSHEET – FORM NIH 2403 – PROPOSAL SUMMARY AND DATA RECORD

SECTION 2 – COST OR PRICE SUPPORT

All related documentation should be included in the proposal in a clearly marked section. Cost and Pricing support should be provided for all proposed subcontractors.

Uniform Cost Assumptions

A) Travel:

1. Assume automobile mileage reimbursement for local travel to/from CTEP offices daily for two contractors traveling separately three times per week.
2. Travel, lodging and per diem for two contract staff to attend one meeting requiring 5 days of overnight travel

B) Assume the contract will provide support for a total of 120 INDs in the CTEP portfolio with 600 protocols (assume a protocol distribution of 40% active, 30% closed to accrual and 30% closed to accrual and treatment) and 65 investigational agents under a Cost Reimbursement Period of Performance plus Fixed Fee mechanism with Equitable Adjustments if additional services are required.

1. Propose one Option to extend the contract for 3 months for transition and Phase-Out purposes. During the Phase-Out period support for Sections 1-4 of the Statement of Work to will continue as well as transition to the successor Contractor.

*Please note that each option should be priced out separately and should be on a separate line item.

C) IND Submissions and Adverse Event workload:

1. Assume 10% of INDs in the CTEP portfolio will be in an electronic format by the start of the contract term with a transition over time to a fully electronic submission
2. Assume 100% of INDs and all FDA submissions will be submitted through the FDA electronic gateway by April 1, 2018.
3. Assume 1300 IND amendments per year
4. Assume a total of 10,000 Adverse Event helpdesk inquiries per year (telephone and E-mail) Help Desk Hours: Monday-Friday 8:30 AM – 5:00 PM ET (except holidays)
5. Assume triage and processing of 5,500 individual Adverse Event reports and 800 24-hour Serious Adverse Event reports per year

D) Software Compatibility:

The contractor shall be responsible for obtaining and maintaining appropriate site licenses for software applications which are compatible with CTEP software, including word processing, reference management, slides, presentations, posters and spreadsheets, etc. to allow seamless flow of information between CTEP and contractor. The current software utilized by CTEP for presentations, word processing, and spreadsheets is Microsoft Office 2010 and Adobe Pro Version 10. The current reference management software compatible with CTEP is EndNote X6.

E) Software License Fees

Over the life of the contract, the Contractor shall be responsible for the payment of annual Insight[®] IND publishing/e-submissions and Rosetta Viewer (an electronic submissions IND viewer) software license fees from contract funds.

The business proposal should assume the payment of \$38,000 total of software license fees the first year of the contract with a cost escalation of 5% per year.

F) Offerors may assume an average of 3 courier deliveries per week at a cost of \$40 per delivery to the FDA and/or other NIH facilities until FDA submissions are fully electronic.

G) Within the framework of a Cost Reimbursement-Period of Performance plus Fixed Fee contract the offerors should indicate the specific labor mix which they consider appropriate for each function outlined in the Statement of Work as well as a 3 month Phase-Out Option to extend the period of performance.

The Government estimates that the work set forth in the Statement of Work of this solicitation shall require approximately 64,390 hours per year (34.25 FTEs) in the first year of the Contract. Contractor transition estimates are 10,058 hours (5.35 FTEs) for a 3 month Phase Out Option. The Government estimates that the work will be performed with a labor mix as comprised below:

BASIC TASK

<u>Labor Category</u>	<u>HOURS/YEAR</u>
Project Manager	1880
Deputy Project Manager	1880
IDB Support Team Manager	1880
Safety Team Manager	1880
Safety Team - Physician	1880
Safety Team - Nurse Specialist	3760
Safety Team Specialist	9400
Safety Team Associate	9400
Clinical Research Professional	11280
IND Regulatory Professional	7520
Regulatory Processing Team Leader	1880
Regulatory Associate	5640
InSight Technical Lead	1880
InSight Publisher	3760
IT Support	<u>470</u>
Total	64,390

Phase Out Option (Contract Extension of 3 months)

<u>Labor Category</u>	<u>HOURS/3 months</u>
Project Manager	470
Deputy Project Manager	470
IDB Support Manager	470
Safety Manager	470
Safety Team - Physician	470
Safety Team - Nurse	940
Safety Team Specialist	940
Safety Team Associate	940
Clinical Research Specialist	940
Regulatory Affairs Specialist	940
Regulatory Team Leader	470
Regulatory Associate	940
Insight Technical Lead	470
Insight Publisher	940
IT Support	<u>188</u>
Total	10,058